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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/465,667	12/17/1999	LENNART CEDGARD	ALBIHN-W-3.3	9154

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/465,667	Cedgart
Examiner	**Art Unit**
Vera Afremova	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Jun 10, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

10. ☐ Other:

Attachment to Advisory Action

Status of claims

Claims 11, 12, 14-27 and 29-32 are pending [Paper No. 20 filed 8/07/2002].

No amendment to the claims has been filed on 6/10/2003 [Paper No. 24] in response to the final rejection [Paper No. 23].

Response to Arguments

Applicants' arguments filed 6/10/2003 [Paper No. 24] have been fully considered but they are not found persuasive for the reasons below.

With regard to the claim rejection under 35 U.S.C. 112, *first paragraph*, applicants appear to argue that the specification does not need to describe every possible combination of elements and one of skill in the art would easily alter the pressure when forming tablets in order to produce the desirable effects (response pages 2-5, especially page 5, par. 1). Yet, this not a question of whether one of skill in the art would be able to alter the pressure but rather what has been done or disclosed by applicants in order to obtain a tablet wherein bacterial viability is "at least about 60 %" as compared to the starting bacterial preparation (suspension or powder). The presently claimed range of tablet friability "between 0.1 and 1.0" is a standard "Good Manufacturing Practice" requirement (specification page 3, line 29) which is a desirable goal but not the applicant's result as disclosed in the as-filed specification. The applicants' particular example discloses that the use of some specific amounts of inulin or fructose oligosaccharide in a tablet material allows to apply a pressure which is sufficient to make a bacterial tablet with 0.3%

friability while still maintaining bacterial viability of at least 60% (example 1, specification page 4). Although it might be obvious that application of a lesser pressure would result in a higher tablet friability including friability of agglomerates or powder wherein light pressure or zero pressure is required, the as-filed specification is missing the disclosure about what has been done (or what amounts of inulin or fructose oligosaccharide have been used) to allow for application of a higher pressure which would be "sufficient" to make a hard tablet with friability 0.1 %, for example, while still maintaining bacterial viability of at least 60%. Thus, while the applicants' generic range of bacterial tablet friability 0.3 % - 0.5 % (specification page 3, line 26) has a written support with regard to a method of making a bacterial tablet by incorporating some specific amounts of inulin and fructo-oligosaccharide as disclosed, the presently claimed range including 0.1 % (or less than 0.3 %), is lacking written support in the as-filed specification as related to a method of making a bacterial tablet by incorporating inulin or fructo-oligosaccharide.

With regard to the claim rejection under 35 U.S.C. 112, *second paragraph*, applicants appear to argue that the term "force sufficient" should be certain because it is properly defined in the specification as being formed by a tablet punching machine (response page 5-7). However, the meaning of this limitation is linked to the issue under 35 U.S.C. 112, *first paragraph.* Although one of ordinary skill in the art might be aware of the operation instructions for the tablet punching machine in order to make a hard tablet with friability according to requirements of Good Manufacturing Practices, the force sufficient to form hard bacterial tablets with bacterial

viability of at least 60% is a result of a combination of particular materials at particular amounts in these hard tablets characterized by bacterial viability of 60%. The combination of elements as presently claimed does not have a sufficient support in the specification. Thus, the "force sufficient" is indefinite within the meaning of the claimed invention.

With regard to the claim rejection under 35 U.S.C. 103(a) applicants argue that there is no suggestion or motivation to combine the cited references and that not all claimed limitations are taught/suggested by the prior art (see response page 8).

This is not found convincing. The prior art demonstrates the use of inulin in dry agglomerates containing viable lactic bacteria {US 5,531,989 [C]}, the use of inulin in pharmaceutical tablets {US 4,021, 545 [E]} and the use of lactic bacteria in dry hard tablets {US 4,806, 368 [B-16]}. The cited prior art provides motivation to use inulin in bacterial tablets as a growth promoting agent for beneficial bacteria and as a superior binder in the pharmaceutical tablets {US 5,422,346 [B]}. The cited prior art provides motivation to make viable bacterial product in a form of tablets because bacterial tablets have better viability than bacterial loose powder {US 4,806, 368 [B-16]}.

The argument that the cited art does not provide a motivation to use inulin as a beneficial agent during method for tablet compression is not convincing because the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the

prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant's argument that the cited prior art does not provide teaching or suggestion of all claimed elements such as " at least 60 %" bacterial viability in a hard tablet with friability of "0.1-1.0" does not appear to have persuasive grounds because the claimed limitations are desirable effects. But the claimed invention is not limited to particular materials including inulin or oligosaccharide at particular amounts which allow for the desirable effects as claimed in bacterial preparations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

July 1, 2003.

Irene Marx

IRENE MARX

PRIMARY EXAMINER